

## **REMARKS**

Claims 1 - 11, and 18 are pending with claims 12-17 withdrawn from consideration.

### **Claim Amendments**

Claim 1 has been amended to recite that the compound of formula I is provided in a certain amount in the claimed antioxidant composition. Support for the claim amendment can be found in the application, as originally filed (for example, please see page 6, paragraphs [0016], [0019], and [0020]). Dependent claims 2-17 have been amended to use language in accordance with conventional U.S. practice. It is submitted that the claim amendments do not add new matter.

### **Restriction Requirement**

The Office Action addresses the search burden issue but does not address Applicants' other arguments in traversal of the restriction. Thus Applicants' repeat the arguments below and urge that they not be ignored.

In response to the Office Action mailed October 28, 2005, and the restriction requirement set forth therein, Applicants elected Group I, claims 1-11 and 18, drawn to antioxidant compositions. Regarding Group II, the methods for preparing the compositions, it is alleged that the method is merely a mixing of the components together and that such mixing was, in general, well known in the art. This fact does not, however, support restriction of this group. This does not support either that (1) the process can be used to make other materially different products or (2) the product can be made by a materially different process. As to (1), the claimed process requires mixing of a component of claim 1. The known processes for mixing, e.g., paints, do not mix such a component as applicants' claim 1. Mixing of different components for making a materially different product is not using applicants' claimed process for such. Regarding (2), there is no allegation of any materially different process for making applicants' compositions. It is further noted that claim 13 is more than merely mixing, i.e., it requires reactions for making the claim 1 compound. Thus, the reasoning in the Office Action does not address support for restricting this claim. Finally, it is urged that the search and examination of the methods for mixing the components to prepare the claimed

compositions would not give rise to a serious additional burden of search; see MPEP §803. If the compositions, based in their broadest embodiment on a single component of formula I, are found novel and nonobvious, it would seem evident that the method for mixing the formula I component to obtain the composition or reacting methods for making the formula I component would necessarily also be novel and nonobvious. For the above reasons, it is urged that the restriction of Group II from Group I should be withdrawn.

#### **Rejection Under 35 U.S.C. § 101**

Claims 1-4 were rejected under 35 U.S.C. § 101 for reciting non-statutory subject matter. Inasmuch as claim 1 is amended by incorporating the limitation of claim 5 into claim 1, the rejection is now moot.

#### **Rejection Under 35 U.S.C. § 112, second paragraph**

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph for lacking a sufficient antecedent basis. The rejection is now moot in view of the claim amendments.

#### **Rejection Under 35 U.S.C. § 102 (b)**

Claims 1-4 currently stand rejected under 35 U.S.C. § 102 (b) as being anticipated by Ulubelen et al. (Phytochemistry, vol. 19, pg. 1761, 1980), Balantine et al. (Phenolic compounds in food and their effects on health I, vol. 506, pg. 102-117, 1992), and Pratt et al. (Phenolic compounds in food and their effects on health II, vol. 507, pg. 54-71, 1992). Applicants' respectfully traverse.

The substance of claim 5 is now incorporated into the amended claim 1, which should render this rejection moot. However, the following comments on the references are provided to further distinguish them from the instant application.

Ulubelen et al describe a process for the extraction and characterization of 6-hydroxyflavonoids isolated from *N. Oaxacana* (see Experimental section at page 1764). Ulubelen neither discloses a composition comprising said hydroxyflavonoid compounds in the same weight proportion as disclosed by the instant application, nor does the reference recite a pharmaceutical, cosmetic, or a nutritional application of the claimed compositions. Furthermore, the cited reference

does not even acknowledge the antioxidant properties of the flavonoid compounds, let alone disclose a composition that underscores such properties.

Balentine's reference discloses phenolic compounds in the tea plant *C. sinensis*. Balentine discusses the various biochemical pathways involved in the *de novo* synthesis of the flavonoid compounds in tea leaves (see page 107, last paragraph) and a method of analyzing polyphenols extracted from *C. sinensis* using HPLC/MS (see page 114, last paragraph). Balentine provides a generic disclosure of the flavone compounds found in tea, but offers no information as to how one of ordinary skill in the art would arrive at the composition claimed in the instant application. Again, Balentine fails to acknowledge the antioxidant properties of the claimed composition, and does not provide any insight into the *pharmaceutical, cosmetic, or nutritional* value of such a composition.

Pratt provides a generic disclosure of the various antioxidants in plant material and discusses the antioxidant activity of plant matter such as genistein or quercetin (see fig. 3 at page 54). Pratt discloses the concentration of such isoflavone compounds in fresh soybeans (see table XI at page 65), but offers no information on how such compositions may be varied to arrive at the formulation claimed by the instant application. Although Pratt suggests that the antioxidant activity maybe enhanced by the combined effect of phenolic compounds in the soy hydrolyzed vegetable protein (pg. 65, lines 14-17), Pratt offers no suggestion as to how the ingredient isoflavones, vitamins, antioxidants, and UV filters could be formulated into a pharmaceutical or cosmetic application, or a nutritional supplementation as claimed by the instant invention (see for example claims 1 and 5-9 of the present application).

Since, all material elements of the claims are not disclosed in any of the cited references, the teachings of Ulubelen, Balentine or Pratt cannot anticipate the composition claimed by the instant invention. Hence, proper withdrawal of the pending rejection is respectfully requested.

#### **Rejection Under 35 U.S.C. § 103 (a)**

The rejection of claims 1-11, and 18 under 35 U.S.C. § 103 (a) as being unpatentable over Ley et al. (US 6,265,611) in view of Predergast et al. (WO 01/03681) and further in view of Jensen et al. (US 2,550,255) is respectfully traversed.

Ley teaches hydroxymandelic acid amides that have potent free radical scavenging and antioxidant properties (col. 2, lines 34-37). The compounds taught by Ley are monocyclic amides (see formula I at col.1), which are *chemically distinct* from the flavonoid compounds claimed by the instant invention. Ley et al. neither disclose an antioxidant composition comprising flavonoid compounds (see claim 7) nor provide any reference as to enable one skilled in the art to substitute the monocyclic amides with the flavonoid compounds claimed by the instant application.

On the other hand, Prendergast discloses a use of flavonoid compounds as an *antiviral or anti-parasitic* agent. The teachings of Prendergast do not make it possible to know whether flavonoid compounds would have the claimed *antioxidant properties* and a capacity to protect body cells from oxidative stress (see claim 7 of the instant application). There is no teaching or suggestion in Prendergast to enable one of ordinary skill in the art to link the antiviral or anti-parasitic effects with the antioxidant effects of these compounds (see the section on “Applications” and “Enumerated embodiments” at page 31 and 34, respectively).

Jensen teaches an antibiotic material from the avocado plant *P. gratissima*, which is capable of inhibiting bacterial growth (see claim 1). Jensen does not disclose the structure of the antibiotic material, nor provide any reference as to teach or suggest that the root of *P. gratissima* could contain the flavonoid compounds of the instant invention. The specific examples and formulations of the claimed antioxidant compositions are not present in Jensen. In fact, Jensen explicitly acknowledges that it is impossible to predict what compounds extracted and purified from the claimed plant material would have the desired biological effects (see col. 1, lines 26-33).

Applicants’ maintain that the teachings of Ley and Prendergast are completely different and it would not be obvious to take the compositions claimed by Ley and add components from Prendergast and/or Jensen therein. Ley only very generally discloses optional use of bactericides or fungicides, among many other possibilities. This provides no suggestion to use any particular one or provide any reasonable expectation that a particular one, such as those of Prendergast, would be useful in an antioxidant composition. Further, Prendergast provides no suggestion that its compounds would be compatible in an antioxidant composition.

Moreover, it is maintained that Ley et al. and the remaining references are directed to nonanalogous art areas, and would not be combined by one of ordinary skill in the art. The test for

non-analogous art is set forth in *In re Clay*, 966 F.2d 656, 23 USPQ2d, 1058 (Fed. Cir. 1992), where the Federal Circuit indicated that there is a two-step test to determine whether references are combinable. First, one must inquire whether the references are in the same field of endeavor. In the present situation, they are not. As noted above, Prendergast discloses compounds with antiviral and/or anti-parasitic effects, and is not directed to the specific needs of compounds disclosed by Ley, which have free-radical scavenging effects.

The second portion of the Clay test is whether the references are "reasonably pertinent to the same problem." As can be seen from the above discussion, they are not, in view of the differing concerns *antiviral effects* versus *antioxidant functions*, as outlined above. Thus, it is submitted that the references are in non-analogous areas, and would not be combined by one of ordinary skill in the art.

Even if all the elements were somehow present, no motivation has been provided to combine the compounds of Ley with the teachings of Prendergast and/or Jensen in such a way as to arrive at the instant invention. Even if the references could be modified to incorporate all the limitations of independent claim 1, the mere fact that the prior art could be modified to arrive at the claimed invention is insufficient. The prior art must convincingly suggest to one of ordinary skill in the art the desirability of the necessary modification. See *In re Laskowski*, 10 U.S.P.Q.2d 1397 (Fed. Cir. 1989). Neither Ley nor Prendergast offer any suggestion which would motivate one of ordinary skill in the art to formulate the claimed compounds into an antioxidant composition in a manner that is presented in the instant application (see Tables 1-3, at pg. 51-59). Accordingly, it is respectfully requested that the rejection be withdrawn.

#### **Obviousness Type-Double Patenting Rejections**

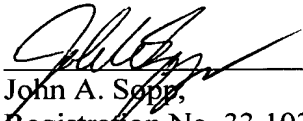
Positive actions to address this rejection at this time would be premature, since no allowable subject matter is indicated in either application. If necessary, applicants will attend to this rejection after allowable matter is identified.

Applicants note however that the compounds of formula I in claims 1 and 11-14 of the co-pending application 10/920,202 do not overlap with the compounds of formula I herein. The R<sup>1</sup> group in formula I of the co-pending application does not include an optionally substituted phenyl

moiety. Accordingly, it is courteously requested that this rejection be withdrawn.

No fee is believed to be due with this response, however, the Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
\_\_\_\_\_  
John A. Sopp,  
Registration No. 33,103  
Attorney for Applicants

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-2753  
Date: May 2, 2006